JAN 4 2006 K052925

510(k) Summary for the SmartPReP2 Centrifuge System for Bone Marrow Processing

Submitter's Name and Address:	Harvest Technologies Corp. 40 Grissom Road, Suite 100 Plymouth, MA
Phone Number: **Telefax Number:**	508-732-7530 503-732-0400
Contact Person:	John D. Bonasera, Director, Regulatory Affairs
Date Summary Prepared:	September 20, 2005
Device Trade Name:	SmartPReP2 Centrifuge System
Common Name:	Centrifuge for Clinical Use
Classification Name:	General Purpose Laboratory Centrifuge Labeled or Promoted for a Specific Medical Use Regulation Number: 21 CFR 862.2050
Substantial Equivalence:	The proposed device is substantially equivalent to SmartPReP Centrifuge System described in K991430 and other table-top centrifuges previously cleared by the FDA via the 510(k) Notification process.
Device Description:	The Harvest Technologies SmartPReP2 System includes a table-top, self-decanting swinging bucket centrifuge. The SmartPReP2 Bone Marrow Procedure Pack includes a Process Disposable and other accessories to allow for separation of cells from bone marrow aspirate.
Intended Use:	The SmartPReP2 Centrifuge System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration compared with the predicate devices.
Performance Testing:	Results of biocompatibility and performance testing have established that the SmartPReP2 System is suitable for the intended use indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 4 2006

Mr. John D. Bonasera
Director of Regulatory Affairs
Harvest Technologies, Corp.
40 Grissom Road
Suite 100
Plymouth, MA 02360

Re: k052925
Trade/Device Name: SmartPReP2 centrifuge System
Regulation Number: 21 CFR 862.2050
Regulation Name: General purpose laboratory equipment labeled or promoted a specific medical use
Regulatory Class: Class II
Product Code: JQC, FMF
Dated: October 14, 2005
Received: October 18, 2005

Dear Mr. Bonasera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings and Precautions section of the devices labeling:

> The safety and effectiveness of this device for in vivo indications for use has not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number if Known: K052925

Device Name: SmartPReP2 Centrifuge System

Indications for Use: The SmartPReP2 Centrifuge System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert A. Becker

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K052925